Atarax®

HYDROXYZINE HYDROCHLORIDE

GlaxoSmithKline

FORMS AND STRENGTHS

Oral forms :

- Box containing 25 film-coated tablets at 10 mg of Hydroxyzine hydrochloride
- Box containing 25 film-coated tablets at 25 mg of Hydroxyzine hydrochloride
- Bottle containing 200 ml of syrup, at 10 mg of Hydroxyzine hydrochloride per 5 ml

Other presentation available :

Box containing 10 and 20 film-coated tablets at 100 mg of Hydroxyzine hydrochloride

ROUTE OF ADMINISTRATION

Oral use

FORMULA

· **Film-coated tablet at 10 mg :** Hydroxyzin. hydrochlorid. 10 mg – Amyl.mayd.– Calc. stear. – Lact. – Polyvidon. – Talc : q.s. ad tablett. compress. un.; Dimethylaminoethylpolymetacrylic. – Macrogol 6000 – Talc. – Titan. dioxyd. obduct.

· **Film-coated tablet at 25 mg :** Hydroxyzin. hydrochlorid. 25 mg – Silic. colloidal. anhydr. – Cellulos. microcristal. – Lact. – Magnes. stear. q.s. ad tablet compress. – Opadry Y-1-7000 (Titan. Dioxyd. – Hydroxypropylmethylcellulose – Macrogol 400 obduct).

· **Syrup at 0.2 % :** Hydroxyzin. bihydrochlorid. 2 mg – Menthol. – Natr. benz. – Sacchar. - Aethanol.– Factit. coryl. avell. odorif. ess (derog. 42/66) –Aqua purificata q.s. ad ml un.

PHARMACOTHERAPEUTIC GROUP

Anxiolytic

Antihistaminic

MANUFACTURER

UCB S.A. Pharma Sector, Chemin du Foriest, B-1420 Braine-l' Alleud · Belgium

Manufactured for :GlaxoSmithKline Export Limited .

INDICATIONS

Due to its sedative, tranquillizing and antihistaminic properties, ATARAX is indicated :

- in the symptomatic relief of anxiety,
- as premedication to general anaesthesia,
- in the symptomatic treatment of pruritus of allergic origin.

CONTRA-INDICATIONS

Hypersensitivity to hydroxyzine.

Intermittent acute porphyria.

INTERACTIONS

The effect of ATARAX may be potentiated by CNS depressants such as narcotics, non-narcotic analgesics, barbiturates and alcohol. Concomitant administration should be avoided or dosage reduced.

When anticoagulants are administered, it is recommended to control hemostasis at the beginning of the treatment.

The administration of ATARAX may interfere with the measurement of urinary 17-hydroxycorticosteroids.

SPECIAL WARNINGS

Because of its anticholinergic action, ATARAX will be used with caution in patients suffering from glaucoma, prostatic hypertrophy, intestinal or urinary obstruction, myasthenia and in case of treatment with MAO inhibitors.

Treatment should be discontinued for minimum one week when cutaneous allergy tests are performed.

Pregnancy and breast feeding

When administered at doses largely higher than the therapeutic doses used in man, hydroxyzine was found teratogenic in mice, rats and rabbits.

Clinical data in man are nevertheless insufficient to guarantee safety during pregnancy.

In one study, administration during pregnancy was associated with an incomplete development of the perceptive faculty in 5-year-old children.

A certain number of cases have been reported concerning new-borns showing postnatal hypotonia, when their mothers had received hydroxyzine during labour.

For these reasons, hydroxyzine should not be administered during pregnancy, except if the attending doctor considers that the benefit/risk ratio is favourable to the foetus. It is recommended not to use hydroxyzine during labour.

In the absence of data on the passage of hydroxyzine in the breastmilk, it is recommended not to give the drug to lactating women.

Driving a car and operating machinery

Vertigo-like sensations and drowsiness during the first days of treatment represent a risk when driving a car or operating dangerous machinery.

Patients should be advised against the simultaneous use of other CNS depressant drugs or food, and particularly alcohol.

INSTRUCTIONS FOR USE

- **Adults :**

In the symptomatic treatment of anxiety :

50 to 100 mg/day : either 2 to 4 tablets of 25 mg per day, or ½ to 1 tablet of 100 mg in the evening at bedtime, in case anxiety is mainly presented as insomnia.

As premedication to general anaesthesia :

100 to 200 mg/day : 1 to 2 tablets of 100 mg at bedtime the night before surgery.

In the symptomatic treatment of pruritus of allergic origin :

30 to 100 mg/day : from 3 tablets of 10 mg to 4 tablets of 25 mg per day.

- **Children from 30 months to 15 years of age :**

The dosage must be adapted to the body weight on the basis of 1 mg/kg/day.

The syrup form should be preferred : 1 coffee spoon = 10 mg

The 100 mg tablet is not suitable for children.

Patients' response to ATARAX being very variable, it is recommended, especially in elderly patients, to start treatment with low doses and to increase them progressively until the adequate dosage is obtained. Dosage should be adapted according to the patient's response to therapy.

For a shorter effect, dosage should be reduced by half. The same applies in case of renal insufficiency.

OVERDOSAGE

The most common manifestation of overdosage is sedation going from a strong drowsiness accompanied with vertigo to sleepiness or a deep and prolonged sleep. There is no specific antidote.

In the management of overdosage, it should be borne in mind that other drugs and particularly CNS depressants may have been taken. If vomiting has not occurred spontaneously, it should be induced.

Immediate gastric lavage is also recommended as soon as possible.

General supportive care, including frequent monitoring of the vital signs and close observation of the patient, is indicated.

In severe cases, classical reanimation monitoring will be undertaken, and hospitalisation is recommended. Epinephrine should not be used.

It is doubtful that hemodialysis would be of any value in the treatment of overdosage. However, if other agents such as barbiturates have been ingested concomitantly, hemodialysis may be indicated. On the contrary, extracorporal hemoperfusion performed with activated charcoal may be useful in cases of severe overdosage. Hydroxyzine may be quantified in biological fluids.

UNDESIRABLE EFFECTS

At the usual doses :

- excessive sedation, drowsiness, vertigo-like sensations due to the depressive action on the central nervous system,
- dry mouth and possible urinary retention due to its anticholinergic effect.

In sensitive patients or when using doses higher than the recommended, involuntary motor activity accompanied with disorders of motor coordination, tremor and convulsions have been reported.

No withdrawal syndrome has been observed when discontinuing treatment.

STORAGE

Store below 25 °C and in a dry place (tablets only).

EXPIRY DATE

The expiry date should be checked. This is indicated on the packing after the word "Exp.".

DATE OF LAST REVISION : June 2002

Should any complaint arise please mention the batch control number indicated on the package.

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